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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,801	10/16/2003	Graham P. Allaway	1900.0380001	5154
26111 7590 01/11/2007 STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER PENG, BO	
			ART UNIT	PAPER NUMBER
			1648	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		01/11/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/685,801	Applicant(s) ALLAWAY ET AL.	
	Examiner Bo Peng	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/26/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-9 and 14-33 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-9,14-18 and 20-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>p.13 of 5/7/04</u> | 6) ☐ Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendment filed October 26, 2006. Claims 5 and 10-13 are cancelled. Claims 1, 2, 4, 6-9, 14-17, 19-25, and 27 are amended. Claim 19 is withdrawn. Claims 28-33 are newly added.
2. Accordingly, Claims 1-4, 6-9 and 14-33 are pending. Claims 1-4, 6-9, 14-18 and 20-33 are considered in this Office action.

Information Disclosure Statement

3. An initialed and dated copy of page 13 of IDS submitted May 7, 2004 is attached to the instant Office action.
4. The rejection of Claim 25 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in view of the amendment to the claims.
5. The rejection of Claims 1-4, 6-9, 14-18 and 20-27 under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement is **maintained**, and now extended to new Claims 28-33.
6. Applicant argues that the instant method is enable for all claimed viruses because they share a common mechanism for inducing membrane fusion, and an artisan of ordinary skill could accurately predict which sequences of an envelope protein are involved in forming the fusion structure, even for viruses that are not closely related to HIV or influenza (Remarks, Paragraph 3, p. 23).

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7. Applicant's argument is considered but not persuasive for following reasons: Although some claimed viruses were suggested or hypothesized to share a common mechanism for inducing membrane fusion as HIV or influenza, the prior art has not demonstrated that is the case. The prior art has not disclosed or characterized any structures of all claimed viruses that are associated with the formation of transient fusion intermediates. As discussed in the previous Office action, the specification has not disclosed any sequences, regions, or structures of all claimed viruses that are associated with the formation of transient fusion intermediates, resulting in the virus entry. The specification has not disclosed any antibodies that can target such transient fusion intermediates of all claimed viruses. There is no evidence that the antibodies, such as T26, 17b, 48d, 8F101 or A32, which target the HIV-1 gp41 six-helix bundle structure, can be used for evaluating the conformational changes of all other viruses. Thus, an artisan of ordinary skill *can not* accurately predict which sequences of any viral envelope proteins are involved in forming the uncharacterized fusion structures without an **undue** amount of experimentation. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

8. The rejection of Claims 1-4, 6-9, 14, 18 and 20-27 under 35 U.S.C. §103, as being obvious over US 6,605,427 and Liang (1998 and 1999), is **maintained, and** now is extended to Claims 26-33 for the following reasons: 8. Applicant argues that US 6,605,427 does not teach or suggest a method in which an envelop protein is contacted with a test compound in the absence of a cellular receptor, nor a method to identify compounds that induce conformations in

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envelope proteins. Moreover, neither Jiang (1998) nor Jiang (1999) cure the deficiencies of the US 6,605,427 (Remarks, Paragraph 4, p. 27 to Paragraph 1, p. 28).

9. Applicant's argument is considered but found to be unpersuasive for following reasons:

10. Jiang (1999) teaches a method for identifying antiviral compounds targeted to the gp41 core structure using a conformation-specific monoclonal antibody (see Title, Paragraph 2, right column, p.86, and 2.5 *ELISA*, p. 88-89). Jiang teaches that a conformation-specific monoclonal antibody was generated, designated NC-1, which specifically binds to the six-helix bundle mimics complex formed by the N and C-peptides, but not to the individual peptides. Jiang teaches that the conformation-specific monoclonal antibody NC-1 can be used in an enzyme linked immunosorbent assay (ELISA) to detect the complex formed with N and C-peptides and for screening of organic compounds for antiviral agents that may interfere with complex formation and thereby inhibit HIV-1 infection. Jiang teaches that the ELISA assay is carried out in the absence of cellular receptor or fragments thereof. (see Paragraph 2, right column, p.86, and 2.5 *ELISA*, p. 88-89). Liang specifically suggests that ELISA assay and NC-1 conformation-specific antibody to gp41 are applicable to rapid screening of libraries of organic compounds for HIV-1 inhibitors targeted to the HIV-1 gp41 core structure (see Abstract).

11. Liang (1999) does not teach explicitly using a membrane-bound HIV envelope protein in his ELISA assay.

12. 6,605,427 teaches to a method for determining the effect of a test compound on the formation of a six-helix bundle intermediate of HIV entry using an HIV envelope protein in the presence of a triggering agent (such as receptor) and a candidate compound to form a mixture, and thereafter measuring the effect that the test compound has on the formation of said

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conformational intermediate using a conformation-specific monoclonal antibody against six-helix bundle intermediate of HIV envelope protein (see Figure 1 and claims).

13. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to identify a compound that induces a conformational changes of HIV envelope protein using either a membrane-bound HIV envelope protein or N-and C-peptides in the assay because N-peptides and C-peptides can form six-helix bundle mimics which reassemble the conformational intermediate structure of the HIV envelope, as taught by Jiang and 6,605,427 (see Fig. 1, Jiang, 1999, p. 87, and Fig. 1, 6,605,427). It would have been further obvious to one of ordinary skill in the art at the time the invention was made that the assay can be carried out in the absence of a trigger agent, such as cellular receptors. One skilled in the art would have been motivated to do so with a reasonable expectation of success, given the knowledge that any compound that induces conformational changes in HIV envelope proteins can be detected in the absence of cellular receptors as taught by Jiang, and also given the knowledge that conformational specific monoclonal antibodies can recognize the six-helix bundle intermediate of the HIV envelope in an assay – either for screening a compound that induces the conformation changes in HIV envelope in the absence of a cellular receptor as a trigger agent, or for screening a compound that affects the conformation changes of HIV envelope in the presence of a cellular receptor as a trigger agent, as taught by Liang and 6,605,427. Therefore, the invention as a whole was *prima facie* obvious over US 6,605,427 and Liang.

14. The rejection of Claims 1-4, 6-9, 14, 18 and 20-25 under the nonstatutory double

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patenting over Claims 1-19 of US patent 6,605,427 **is maintained**, and now is extended to Claims 26-33, and in view of Liang (1999). **Introduction of Liang's reference is necessitated by Applicant's amendment.**

15. Applicant argues that the pending claims are distinct from the claims of 6,605,427 because 6,605,427 require the use of triggering agents, virus permissive cells, or receptors, while the pending claims, as presently amended, require the absence of such reagents (Remarks, Paragraph 2, p. 24).

16. Applicant's argument is not convincing for following reasons:

17. The relevance of Jiang (1999) is set forth *supra*. Jiang teaches that the ELISA assay for screening antiviral compounds targeted to the gp41 core structure is carried out in the absence of cellular receptor or fragments thereof. (see Paragraph 2, right column, p.86, and 2.5 *ELISA*, p. 88-89).

18. It would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out the assay in the absence of a trigger agent, such as cellular receptors. One skilled in the art would have been motivated to do so with a reasonable expectation of success, given the knowledge that any compound that induces conformational changes in HIV envelope proteins can be detected in the absence of cellular receptors as taught by Jiang, and also given the knowledge that conformational-specific monoclonal antibodies can recognize the six-helix bundle intermediate of the HIV envelope in an assay either for screening a compound that induce the conformation changes of the HIV envelope in the absence of a cellular receptor as a trigger agent, or for screening a compound that affects the conformation changes of the HIV envelope in the presence of a cellular receptor as a trigger agent, as taught by Liang and 6,605,427.

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Therefore, the instant Claims 1-4, 6-9, 14, 18 and 20-33 as a whole were *prima facie* obvious over US 6,605,427 and Liang.

19. **The following are new ground rejections necessitated by Applicant's amendment set forth in this Office action:**

Claim Rejections - 35 USC § 112, first paragraph

20. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

21. Claims 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

22. Please note that the newly amended scope "in the presence of one or more cellular receptors or fragments thereof, wherein said cellular receptors or fragments thereof do not induce said conformational change" is NEW MATTER. This new limitation is not presented in the original Claims and is not supported by the instant specification. Removal of all new matter is required. *In re Russsmussen* 210 USPQ 325.

Remarks

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23. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BP

Bo Peng, Ph.D.
January 3, 2007


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SUPERVISORY PATENT EXAMINER
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